

PATENT
Attorney Docket No.: DIVER1380-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Applicant: Jay M. Short Art Unit: 1636
Serial No.: 09/529,458 Examiner B. Loeb
Filed: April 13, 2000
Title: SCREENING FOR NOVEL COMPOUNDS WHICH REGULATE BIOLOGICAL INTERACTIONS

Commissioner for Patents
Washington, D.C. 20231

Considered
that 6/14/02

DECLARATION UNDER 37 C.F.R. § 1.132

1. I, Jay Short, declare that I am the inventor of the above-identified patent application.

2. I have reviewed the Final Office Action mailed November 6, 2001 and I understand that the Examiner has alleged that while the application is enabling for performing the method of the invention in a cell, and with gene expression of a reporter gene as the basis of the detectable signal, the specification allegedly does not reasonably provide enablement for performing the method in a cell with a non-gene expression based detectable signal or for performing the method *in vitro* with either type of detectable signal.

3. I have demonstrated, as well as others working under my direction and supervision, that in addition to detecting reporter gene expression, cell growth, or inhibition of cell growth, can also be utilized as a detectable signal for interaction of two molecules or interference with the interaction of two molecules in the method of the invention. For example, as shown in Figures 1 and 2 of this declaration, when two regions of dihydrofolate reductase (DHFR) protein are allowed to interact via plasmids containing Fos and Jun genes and their interacting regions, (referred to as the "bait" and "target" in Figure 1) in a DHFR deficient host cell, in the absence of an inhibitor, cell growth is unaffected and the host cell survives. In contrast, in a DHFR deficient host cell, when the interaction between the two regions of DHFR are disrupted by a

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third molecule, for example from a mixed population library, the host cell growth is affected since there is no DHFR activity in the cell and the cell dies. This screening method allows one to measure the effect of a third molecule on the interaction of two other molecules in the absence of detection of expression of a gene as a reporter molecule.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code, and that such willful statements may jeopardize the validity of the application or any patent issuing therefrom.

May 6, 2002
Date:

Jay M. Short, Ph.D.

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